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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

JUN 24 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-14

Howard R. Eldridge, RPh.
Grandview Pharmacy, Inc.
2230 Park Road
Connersville, Indiana 47331

Dear Mr. Eldridge:

Investigator Jerry Corwin of our Cincinnati District office inspected Grandview Pharmacy, Inc. 2230 Park Road Connersville, Indiana on June 5 and 8, 1998. The medical oxygen manufactured by this firm is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (The Act).

Oxygen, USP is a drug within the meaning of Section 201(g) of the Act.

The medical oxygen is adulterated, in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (Title 21, Code of Federal Regulations, Parts 210 and 211), such as:

1) Failure to adequately test each batch of Oxygen, USP for conformance to final specifications prior to release. [21CFR 211.165(a)]

   For example there is no record of testing compressed Oxygen, USP cylinders for four years.

   Incoming liquid oxygen is not tested for identity and strength prior to filling the liquid Oxygen USP home units.

2) Failure to properly calibrate instruments and gauges. [21CFR 211.160(b)(4)]

   For example an acceptable calibration standard was not available for the Oxygen Analyzer in that Nitrogen used to set the "zero" on the meter did not have a Certificate of Analysis, which certified high purity.

3) Failure to establish detailed written procedures for production and process controls covering all aspects of your operation. [21 CFR 211.100(a)]

4) Failure to establish strict control over labeling issuance. [21 CFR 211.125]

5) Failure to establish written procedures assuring that correct labels are used, including the assigning of a lot number. [21 CFR 211.130(b)].

6) Failure to establish adequate batch production and control records for each batch of Oxygen USP produced. [21 CFR 211.188(b)].

7) Failure to review all production and control records by the quality control unit prior to the release and distribution of Oxygen, USP. [21 CFR 211.192]

8) Failure to maintain complete records of the periodic calibration of the oxygen analyzer and pressure gauges. [21CFR 211.194(d)].

9) Failure to assure and document that each person engaged in the transfilling and testing of Oxygen, USP had the education, training or experience to enable that individual to perform the assigned function. [21CFR 211.25]

The above is not intended to be an all-inclusive list of violations at your firm. It is your responsibility to assure that your firm's products adhere to the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct these violations and to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. Your response should be directed to the attention of Mrs. Judith A. Putz, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Avenue, Detroit, Michigan 48207 (Telephone: 313-226-6260 ext. 137).

Sincerely yours,

John P. Dempster

for Raymond V. Mlecko
Acting District Director
Detroit District